



# CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

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January 7, 2014

By FedEx and Email

Ms. Lynn Vendinello  
Chief, Fibers and Organics Branch  
Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
National Program Chemicals Division  
1200 Pennsylvania Avenue N.W.  
Document Control Office (Room 6428)  
Washington, DC 20460-0001

**Re: Comments of the Color Pigments Manufacturers  
Association, Inc. Regarding A Table Entitled  
"METI Report, May 2013"**

Dear Ms. Vendinello:

This letter is provided on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to your email of September 30, 2013.

The CPMA is an industry trade association representing small, medium and large color pigments manufacturers throughout Canada, Mexico and the United States, accounting for the bulk of the production of color pigments in these countries. Color pigments manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, cement products, textiles, cosmetics and artist products.

CPMA members comply with the regulations and requirements applicable to their businesses. In particular, CPMA members comply with the requirements set forth in the EPA regulations promulgated pursuant to the Toxic Substances Control Act ("TSCA") and do not manufacture or import pigments for sale and use in the United States which exceed the established limits.

#### **Introduction and Background on the METI Investigation**

Your September 30, 2013 email requested information related to the Japanese Ministry of Economy, Trade and Industry ("METI") and a list of pigment products on a table entitled "METI Report, May 2013" (the "Table"). METI has published a series of detailed press releases regarding an investigation of "Organic Pigments That Can Unintentionally Contain Polychlorinated Biphenyl ("PCB") (the "METI Investigation") in Japan. In one of its last press releases, on May 10, 2013, METI also published a notice to Japanese industry available only in Japanese. An unofficial translation indicates that the notice is entitled "(10<sup>th</sup> of May 2013) Organic Pigments Which Were Found with PCBs Generated as a By-product at More than 50ppm". The notice to industry identifies those specific pigments, which METI has instructed responsible companies in Japan to remove from the market and recall from customers. The notice also identifies the name of responsible companies, generic pigment names, company specific product names, primary uses for the recalled pigments and, in some cases, the identity of reselling customers. Instructions are also provided to discontinue production, report shipments and recover the products. In each case, the notice refers to a

specific lot of pigment from a specific supplier and does not impact other lots of the same product or products from other companies based upon the same Colour Index pigment name.

The Table about which you have inquired appears to have been derived from the METI notice to Japanese industry. We do not know who prepared the Table.

The METI Investigation was conducted by the Chemical Management Policy Division, Manufacturing Industries Bureau within METI. The METI Investigation represents an on-going voluntary project in Japan to collect information (as stated by METI) on "unintentional PCBs" contained in pigments. Pigments are defined by METI as:

"water-insoluble or oil-insoluble powder used for coloring. Organic pigments are those comprising organic compounds."

The METI Investigation and the actions taken by METI are the result of international industry efforts and publications. METI states in its February 10, 2012 press release that:

"In January 2011, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) published a report saying that PCB can be unintentionally generated in the manufacturing processes of certain organic pigments. Following this report, members of JDICA voluntarily conducted investigations and found some cases where PCB was unintentionally generated as a byproduct. They reported the results of the investigation to METI on February 1 this year."

METI has indicated that it will be taking action to remove from the Japanese market any pigments found to contain PCBs in excess of the 50 part per million ("PPM") standard. METI has

stated that it will take the following actions in response to its survey:

"If it is found that, as the result of analysis, certain organic pigments contain PCB exceeding the concentration of 0.005% (50 ppm), i.e. the level over which distribution of the product should be suspended under the Stockholm Convention on Persistent Organic Pollutants (POPs convention), METI will take the following measures (Administrative guidance).

METI will request the manufacturers and importers to stop manufacture, import and shipment unless concentration reduction measures to continuously keep the concentration not more than 50 ppm is confirmed by the administrative authority;

METI will request the concerned manufacturers and importers to collect the organic pigments in question and keep them appropriately until their disposal.

METI will request the customers identified by the report from the manufacturers or importers to stop using the organic pigment and to cooperate in collection by the manufacturers and importers.

If the organic pigments have already been shipped and used as a constituent of paint or the like, the dilution ratio of the substance would be changed to ten times that for the status of pigment. Therefore, METI considers that no problems would occur even if the paint is continuously used. To be sure, however, METI will have experts evaluate risks when the use of the product is continued."

The following is a list of the links to the METI Press Releases reporting on organic pigments that can contain "unintentional PCBs":

February, 2012, "Organic Pigments That Can  
Unintentionally Contain Polychlorinated  
Biphenyl":

[http://www.meti.go.jp/english/press/2012/0210\\_04.html](http://www.meti.go.jp/english/press/2012/0210_04.html)

February, 2012, "Organic Pigments That Can  
Unintentionally Contain Polychlorinated Biphenyl  
(Second Report)":

[http://www.meti.go.jp/english/press/2012/0217\\_04.html](http://www.meti.go.jp/english/press/2012/0217_04.html)

March, 2012, "Organic Pigments That Can  
Unintentionally Contain Polychlorinated Biphenyl  
(Report No. 3)":

[http://www.meti.go.jp/english/press/2012/0316\\_03.html](http://www.meti.go.jp/english/press/2012/0316_03.html)

April, 2012, "Administrative Guidance on  
Manufacture, Import, etc. of Organic Pigments that  
can Unintentionally Contain Polychlorinated Biphenyl  
(Fourth Report)":

[http://www.meti.go.jp/english/press/2012/0420\\_02.html](http://www.meti.go.jp/english/press/2012/0420_02.html)

May 2012, "Summarized Results of the First  
Investigation into the Presence of Polychlorinated  
Biphenyl (PCB) as Byproducts in Organic Pigments":

[http://www.meti.go.jp/english/press/2012/0528\\_02.html](http://www.meti.go.jp/english/press/2012/0528_02.html)

September, 2012 "Administrative Guidance on  
Manufacture, Import, etc. of Organic Pigments that  
can Unintentionally Contain Polychlorinated  
Biphenyls (Fifth Report)":

[http://www.meti.go.jp/english/press/2012/0906\\_02.html](http://www.meti.go.jp/english/press/2012/0906_02.html)

March 2013, "Administrative Guidance on Manufacture,  
Import, etc. of Organic Pigments that can  
Unintentionally Contain Polychlorinated Biphenyls  
(Sixth Report)":

[http://www.meti.go.jp/english/press/2013/0322\\_03.html](http://www.meti.go.jp/english/press/2013/0322_03.html)

May, 2013, "Administrative Guidance on Manufacture,  
Import, etc. of Organic Pigments that can

Unintentionally Contain Polychlorinated Biphenyls  
(Seventh Report)":

[http://www.meti.go.jp/english/press/2013/0510\\_02.html](http://www.meti.go.jp/english/press/2013/0510_02.html)

#### **CPMA Comments on the Table**

CPMA believes that the limited information derived from the METI notice to Japanese industry and contained in the Table of 17 samples which were recalled from commerce has been taken out of context, when compared to the larger METI Investigation which was described in detail in the press statements. The press releases issued by METI describe the METI Investigation in detail and provide a synopsis of the overall METI Investigation. The press releases were published on the internet in English. The notice to Japanese industry regarding the 17 samples subject to recall is only available for download in Japanese.

As you are aware, the analysis of PCBs in complex solid matrices at such low levels is difficult; and laboratory preparation methods and choice of standards can have a significant impact, which could result in either overestimating or underestimating the PCBs present in a sample. Although METI provides some guidance on the preferred laboratory methods, the detailed methods that were used to analyze the 17 samples which are shown to have exceeded 50 PPM are not known. Additionally, we do not know the production process used to produce the 17 samples tested or country of origin for the represented manufacturing process. It is our understanding that the analytical methods used to test these 17 samples were developed individually by each participating company. Without answers to

these questions, it would not be possible to determine the reliability of the represented data.

By focusing only on the 17 samples which were recalled by METI, without reference to the detailed description of the ongoing investigation being undertaken by METI and industry, a biased view is presented which unnecessarily raises concern. Based on the complete press releases from METI, the 17 samples exceeding 50 PPM are outliers representing less than 3% of samples collected by METI and detailed in its press release statements.

According to the press release statements from METI, a total of 588 samples were collected in the METI investigation. Of these, 359 samples were measured for PCB concentration and found to contain no measurable PCBs, using a detection limit of .5PPM. An additional 212 samples of the 588 total were analyzed for PCB concentrations and found to contain PCBs in the range of .5 to 50 PPM. All of the data represented by the 17 samples appears to be derived from no more than four companies, and nine of the samples were associated with one company. CPMA members are not aware of any United States imports of the pigment production batches represented by the 17 pigment samples identified in the Table and which METI directed to be recalled.

Additionally, if the reader reviews press releases which describe the METI Investigation, the total quantity of pigments represented by the 17 outlier samples involves a very small total quantity of pigments in Japanese commerce. In total, for all products represented by the 17 outlier samples, there were fewer than 14 metric tons of pigments. This is in comparison to

an estimate of 35,749 metric tons of organic pigments manufactured or imported in commerce in Japan in 2012, based upon data reported by METI.

Therefore, on further review of the press releases published by METI, we see a very small number of samples from four companies which were found to exceed the 50 PPM limit, and this small sample represents a very small portion of pigments in commerce in Japan. It would appear that the vast majority of Japanese industry is doing a very good job of monitoring PCBs and complying with required limits.

METI is taking a cautious approach by identifying and eliminating pigments which exceed the 50 PPM limit. It is our understanding that METI intends to promulgate the new rules limiting unintentional PCBS in pigments. Furthermore, METI has stated that, for any products found to exceed the 50 PPM limit, the business concerned will be instructed to suspend manufacture, import and shipment of the pigments. METI has also taken additional steps to require the collection of unused pigments which exceed the 50 PPM limit from customer companies to which the products were shipped. It does not appear that any pigments which exceed the 50 PPM limit are circulating in Japanese commerce.

CPMA members have not been given information from suppliers that there have been any shipments from Japan to the United States which exceed 50 PPM. Under the METI policy, our members would be required to collect and return pigments which exceed 50 PPM, if such shipments were made.



### **Inadvertent Monochlorobiphenyl and Dichlorobiphenyl Congeners**

The regulation of monochlorobiphenyl and dichlorobiphenyl congeners is undertaken differently in various national and international regulatory programs. For purposes of the METI Investigation, these congeners were included and reported as PCBs, in a manner the same as all other congeners.

In many countries, the term "PCBs" is not defined to include these congeners. The prefix "Poly", literally meaning "many", is understood to contain three or more of an entity, in this case chlorine atoms. The "Mono" and "Di" congeners are also not considered to be toxicologically equivalent to PCBs containing three or more chlorine atoms.

Monochlorobiphenyl and dichlorobiphenyl congeners are regulated in the United States with a special discounting factor only for the inadvertent presence in products. Therefore, even though some of the 17 samples may be considered compliant in the United States and other jurisdictions, METI has determined not to exclude or discount these congeners. It is not clear that METI has yet determined a final policy on the presence of these congeners in pigments going forward.

### **CPMA Communication with METI**

In December of 2012, Ms. Erica Uchino, the Deputy Director of the Chemical Safety Office in the Chemical Management Policy Division of METI, requested information from industry groups regarding the prevailing regulations applicable to PCBs in jurisdictions outside of Japan. Upon learning of the request, CPMA volunteered assistance with respect to the current

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regulations in Canada and in the United States. A copy of our response to MS. Uchino, dated March 13, 2013, and the reference materials attached to it are enclosed for your review. We noted in our response that the United States regulations were the result of a consensus proposal put forward by the Chemical Manufacturers Association, the Environmental Defense Fund and the Natural Resource Defense Council. The background and reasoning in favor of the consensus proposal are explained in the Preamble to the Federal Register of July 10, 1984, which is included in the enclosed materials.

#### **Conclusion**

CPMA members comply with the requirements set forth in the EPA regulations promulgated pursuant to TSCA and do not manufacture or import pigments for sale and use in the United States which exceed the established limits. Our members are not aware of pigment products or colored products from Japan entering the United States market in violation of the TSCA regulations for PCBs.

Since 1978, EPA has evaluated both the toxicity of, and exposure to, PCBs in promulgating the various use authorizations. For pigments specifically, EPA concluded that:

"The rule authorizes the use of diarylide and phthalocyanine pigments containing more than 50 ppm PCB until January 1, 1982, and the processing and distribution in commerce of these pigments until July 1, 1979...These products contain far less than 50 ppm PCB because the dilution that takes place when the pigment is mixed with the medium it is coloring. As a result, the health and environmental risks are not unreasonable...the industry is changing its

processes to reduce the level of PCB contamination to below 50 ppm in the next two years. At the present time these particular pigments are a major segment of the pigment market. For example, diarylide pigments form about 80% of the yellow pigment market. This ban will, therefore effect a substantial number of pigment related industries." [Emphasis Added] 44 Fed. Reg. 31535

In order to grant such an authorization, in the final rule in 1979, EPA was required to determine that, "granting such an authorization would not present an unreasonable risk to health or the environment". 43 Fed. Reg. 24811(1978).

Virtually any synthetic organic chemical product containing chlorine may contain traces of inadvertent PCBs. EPA has in past rulemaking proceedings reviewed many such products. See for example 40 CFR §761.3, which specifies a separate specific standard for detergent bars, and the conclusions reached by EPA when the current regulations were considered:

"A(2) Certain organic compounds may contain trace amounts of PCB's despite the use of carefully controlled process manufacturing processes. With careful manufacture such compounds will contain less than 50 ppm of PCB. All of the diffuse and extremely numerous PCB sources below 50 ppm cannot practically be dealt with by EPA. A cutoff of 50 ppm has the advantage of limiting EPA administration and enforcement to a manageable number of PCB sources, thus ensuring the maximum effectiveness of the regulation." 43 Fed. Reg. 24804.

Since there are "diffuse and extremely numerous PCB sources" in products, we do not understand the focus by any group solely on pigments or on what appear to be aberrational samples. Our members have actively complied with the

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requirements of the regulations, since the TSCA regulations were first promulgated based on the consensus proposal by EPA in 1984. If you or your colleagues require further information, please call me at the number provided above.

Sincerely yours,



J. Lawrence Robinson  
President